DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

MN2092N

PURGED

cc: HFI-35
DWA

October 19, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 03

Ronald D. Whitt
President
Chemrite Industries, Inc.
19725 West Edgewood Drive
Lannon, Wisconsin 53046

Dear Mr. Whitt:

During our inspection on September 28-30, 1999, October 1, 1999 and October 6, 1999, of your over-the-counter (OTC) drug manufacturing facility located in Lannon, WI, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your antibacterial soap is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Your OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)] in that your process validation has not been completed.

2. Failure to establish written procedures for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product [21 CFR 21.67(b)].

3. Failure to assure that each person responsible for supervising the manufacture, processing, packing, and holding of a drug product has the education, training, and experience to perform the assigned functions [21

CFR 211.25(b)) in that training of management personnel is inadequate. No formal GMP training conducted by qualified individuals has been conducted.

4. Failure of the quality control unit to approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product [21 CFR 211.22(c)] in that written procedures are not independently reviewed and approved by the quality control unit.

5. Failure to assure uniformity from batch to batch by having master production and control records for each batch of drug product, including each batch size [21 CFR 211.186] in that master production and control records have not been prepared for any product batch size.

6. Failure to determine actual yields and percentages of theoretical yields at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall be performed by one person and independently verified by a second person [21 CFR 211.103].

In addition, the regulations define a lot number, control number, or batch number as any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined [21 CFR 210.3(b)(11)]. Co-mingling of batches does not allow for the complete history of the "lot" of product to be determined.

Also, if your OTC drug product is exempt from having an expiration date, your reserve samples shall be retained for three years after distribution of the last lot of the drug product containing the active ingredient. OTC drug products are exempt from having an expiration date if the following criteria are met: (a) the labeling does not bear dosage limitations; (b) the product is stable for at least three years as supported by the appropriate stability data.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that the Food and Drug Administration expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to Compliance Officer Carrie Hoffman at the address on the letterhead.

Based on the re-current GMP problems cited in Warning Letter issued to your firm in 1996, the forms FDA-483 issued to your firm in July 1996, June 1997, and October 1999, we believe it is prudent to have you meet with us in our Minneapolis Office. We have scheduled a meeting for Thursday, November 4, 1999 at 1:00 p.m. Please bring copies of documentation demonstrating that corrections have been made. If the meeting arrangements conflict with your schedule, please contact Ms. Hoffman at (612) 334-4100 ext. 159 to make other arrangements.

Sincerely,

Cheryl A Bigham

Cheryl A Bigham
Acting Director
Minneapolis District

CAH/ccl